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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,499	09/23/2003	Chris D. Paulse	016866-006211US	3983
20350	7590	09/14/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			LAU, TUNG S	
			ART UNIT	PAPER NUMBER
			2863	

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/669,499	Applicant(s) PAULSE ET AL.	
	Examiner Tung S Lau	Art Unit 2863	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-45, 48-56 and 59-62 is/are rejected.
- 7) ☒ Claim(s) 46, 47, 57 and 58 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1-20-2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. Information Disclosure Statement filed on 1-20-2004 is acknowledged by the examiner; A copy of a signed PTO-1449 attached with this office action.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39-45, 48, 50-56, 59, 60, 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Karger et al. (U.S. Patent Application Publication 2003/0034450).

Regarding claim 39:

Karger discloses a method for analyzing mass spectra the method comprising:

(a) detecting signals including signal intensity in a plurality of spectra wherein each spectra in the plurality of comprises data representing signal as a function of time-to-flight, mass-to-charge-ratio, or value derive from time-to-flights or mass-to-charge-ratio (page 1-2, section 0009-0011). (b) forming at least one signal cluster by clustering signal with similar time-of-flights, mass-to charge-ratio, or value derived from time-of-flights or mass-to-charge-ratios (page 3, section 0033); (c) selecting one or more signal cluster from the plurality of signal

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clusters if the number of signals in a signal cluster exceeds a predetermined number of signals (page 8, section 0075); and (d) selecting the time-of-flights, the mass-to-charge-ratio, or the value derived from the time-of-flights, the mass-to-charge-ratio of the selected one or more signal cluster in (c) (page 9, section 0078, table 2).

Regarding claim 50:

Karger discloses a computer readable medium comprising: (a) code for detecting signals including signal intensities in a plurality of spectra, wherein each spectrum in the plurality of spectra comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio (page 9, section 0078, table 2); (b) code for forming at least one signal cluster by clustering signals with similar time-of-flights, mass-to-charge ratios, or values derived from time-of-flights or mass-to-charge ratios (page 3, section 0033); (c) code for selecting one or more signal clusters from the plurality of signal clusters if the number of signals in a signal cluster exceeds a predetermined number of signals (page 8, section 0075); and (d) code for selecting the time-of-flights, the mass-to-charge ratios, or the values derived from the time-of-flights or the mass-to-charge ratios of the selected one or more signal clusters (page 9, section 0078, table 2).

Regarding claim 60:

Karger discloses a computer readable medium for classifying an unknown sample into a class characterized by a biological status using a digital computer,

the computer readable medium comprising: (a) coda for entering data from a mass spectrum of the unknown sample into a digital computer (page 7, section 0067), and (b) code for processing the mass spectrum data using a classification model to classify an unknown sample in a class characterized by a biological status, wherein the classification model is formed by a process including (i) detecting signals including signal intensities in a plurality of spectra, wherein each spectrum in the plurality of spectra comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio (page 1-2, section 0009-0011, page 9, section 0078, table 2), (ii) forming a plurality of signal clusters by clustering signals with similar time-of-flights, mass-to-charge ratios, or values derived from time-of-flights or mass-to-charge ratios (page 9, section 0078, table 2), (iii) selecting one or more signal clusters from the plurality of signal clusters, if the number of signals in a signal cluster exceeds a predetermined number of signals (page 8, section 0075, page 9, section 0078, table 2), (iv) selecting the time-of-flights, the mass-to-charge ratios, or the values derived from the time-of-flights or the mass-to-charge ratios of the selected one or more signal clusters in (iii) (page 1-2, section 0009-0011, page 9, section 0078, table 2), and (v) forming a second plurality of mass spectra, wherein the second plurality of mass spectra is formed using the time-of-flights, the mass-to-charge ratios, or the values derived from the time-of-flights or the mass-to-charge ratios selected in (iv) (page 1-2, section 0009-0011, page 9, section 0078, table 2).

Regarding claim 41, Karger discloses the intensity of the signal (page 9, section 0078); Regarding claim 42, Karger discloses class of samples to class of biological status (page 1, section 003-004, page 9, table 2); Regarding claims 43, 54, Karger discloses a class discriminating between the class (page 9, table 2); Regarding claims 44, 51, Karger discloses analyzing data from second sample (page 8, section 0075, page 1-2, section 0009-0010); Regarding claims 45, 56, Karger discloses a process is recursive partitioning process (page 1-2, section 0009-0010); Regarding claim 48, Karger discloses entering sample in a digital computer (page 7, section 0067), processing unknown sample using classification biological status (page 8, section 0075, page 9, section 0078, table 2); Regarding claim 52, 55, Karger discloses computer code to run the program (page 7, section 67); Regarding claim 53, Karger discloses using plurality of sample with class set of biological sample (page 9, section 0078, table 2, page 1, section 0003-0004); Regarding claims 59, 62, Karger discloses a gas phase ion spectrometer (page 1-2, section 0009-0011, page 2, section 28) and a digital computer (page 7, section 0067).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 49 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Karger et al. (U.S. Patent Application Publication 2003/0034450) in view of Nelson et al. (U.S. Patent Application publication 2001/0021535).

Karger discloses a method and computer medium including the subject matter discussed above except detecting class by disease, Nelson discloses detecting class by disease (page 9-10, section 0106) in order to detect any antigens or antibodies in a specimen (page 1, section 0012).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Karger to have the detect class by disease taught by Nelson in order in order to detect any antigens or antibodies in a specimen (page 1, section 0012).

Claim Objections

4. Claims 46, 47, 57, 58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitation of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance: prior art fail to teach the process is a neural network, the second mass spectra by adding estimates for missing signals.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should

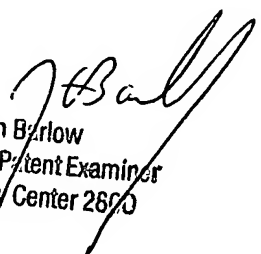
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preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tung S Lau whose telephone number is 571-272-2274. The examiner can normally be reached on M-F 9-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on 571-272-2269. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TL


John Barlow
Supervisory Patent Examiner
Technology Center 2863